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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,216	01/04/2002	E. Antonio Chiocca	0609.5050005/JAG/KRM/FRC	3452
26111	7590	09/14/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			GARVEY, TARA L	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/035,216	Applicant(s) CHIOCCA ET AL.	
	Examiner Tara L Garvey	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 4-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/26/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/26/02, 5/31/02, 7/17/02</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-37 are pending.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-3) in the reply filed on July 27, 2004 is acknowledged.

Claims 4-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 27, 2004.

Information Disclosure Statement

The information disclosure statement filed 7/17/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claim 1 is objected to because of the following informalities: "Herpes virus" should be spelled "herpesvirus". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "herpes simplex virus (HSV)-based amplicon vector" is indefinite. The use of the word "based" makes it unclear as to what needs to be contained within the vector.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "viral-based vector" is indefinite. The use of the word "based" makes it unclear as to what needs to be contained within the vector.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Vos et al (US Patent 5,275,942).

Claim 1 is drawn to an amplicon vector comprised of a large capacity cloning vector, a herpesvirus origin of replication, a herpesvirus cleavage/packaging signal and a genomic DNA fragment that is capable of infectious delivery of the DNA to a cell. Claim 2 limits the invention of claim 1 to the cloning vector being a BAC, PAC, YAC, MAC, HAC, cosmid or viral-based vector.

Vos et al teaches an EBV plasmid vector that contains a herpesvirus origin of replication such as oriP and oriLyt and a DNA cleavage a packaging signal such as the fused long terminal repeat region (TR) (column 5 lines 19-26). They also teach the cloning vector containing fragments of genomic DNA that are over 100 kb in length (column 2, lines 21-22, column 4 lines 30-31 and 55-57, column 6 lines 13-16). Finally, they teach that these plasmids can be used for the production of infectious virions for the delivery of the DNA to cells (column 4 lines 66-68 bridging column 5 lines 1-4 and columns 12-13, example 10). Thus, Vos et al teach all that is recited in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vos et al in view of Horsburgh et al (US Patent 6,277,621).

Claims 1 and 2 have been described previously. Claim 3 limits the invention of claim 2 to the large capacity cloning vector being a BAC or a PAC.

Vos et al teaches the large capacity cloning vector as a viral-based vector, but does not teach the use of other cloning vectors such as a bacterial artificial chromosome (BAC), P1 phage artificial chromosome (PAC), yeast artificial chromosome (YAC), mammalian artificial chromosome (MAC), human artificial chromosome (HAC) or cosmid. Horsburgh et al demonstrate that BACs, PACs, YACs, MACs and HACs are suitable large capacity cloning vectors for viral and genomic DNA inserts (column 3 lines 17-66, column 4 lines 57-60 and column 6 lines 27-47 and 61-64). It would have been obvious to one of ordinary skill in the art to modify the teachings of Vos et al to use one of these cloning vectors as a viral-base amplicon vector because Vos et al teach that at the time of the invention that it is within the skill of the art to maintain viral and genomic DNA in a cloning vector capable of containing large fragments of DNA. One would have been motivated to do so in order to receive the expected benefit of, as suggested by Vos et al and actually exemplified by Horsburgh et al, of stably maintaining viral and genomic DNA fragments in various artificial chromosome cloning vectors. Absent of any evidence to the contrary, there would have been a reasonable expectation of success in using one of these artificial chromosome as

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a cloning vector since it is known that these vectors can stably maintain large inserts of DNA.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent

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number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey
Examiner
Art Unit 1636

TLG



JAMES KETTER
PRIMARY EXAMINER